

JUN 16 2005

K050910

pg 1 of 3

510(k) SUMMARY

**Roei Medical Technology, Ltd.'s
Roei Working Element and Roei Cutting Loops**

**Submitter's Name, Address, Telephone Number, Contact Person
and Date Prepared**

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Contact Person: Jonathan S. Kahan

Date Prepared: April , 2005

Name of Device and Name/Address of Sponsor

Roei Working Element and Roei Cutting Loops
Roei Medical Technologies, Ltd.
The Herzeliyah Business Park
85 Medinat Hayehudim Street
Tower G, 8th Floor
Israel

Phone: 011-972-9-970-1822
Facsimile: 011-972-9-970-1866

Common or Usual Name

Urological Resectoscope Accessories

Classification Name

Resectoscope, Working Element. Endoscope and Accessories.
Endoscopic electrosurgical unit and accessories

K 050910
pg 2083

Predicate Devices

- Karl Storz Endoscopy - America, Inc.'s Resectoscopes Working Element and Cutting Loop Components (K954050)
- Richard Wolf Medical Instruments Corporation's Resectoscope E-Line series Working Element and Cutting Loop Components (K980302)
- ACMI's Resectoscope Working Elements and Cutting Loop Components (preamendment and K951972)
- Olympus Winter & IBE's Olympus Working Element (K992141)
- American Medical Systems, Inc.'s AMS Coaguloop Resection Electrodes (K991314 and K971512)
- ACMI's VaporTrode™ and VaporTome™ Resection Electrodes (K973820)
- Karl Storz's KSEA Vaporization Electrodes (K961706)

Intended Use / Indications for Use

The Roei Working Element and Roei Cutting Loops are endoscopic electrosurgical accessories intended for use with monopolar resectoscope systems for the resection of soft tissue in transurethral bladder tumor resection (TURBT), transurethral prostatic and bladder biopsy, and transurethral resection of the prostate (TURP) procedures.

Technological Characteristics

The Roei Working Element and Cutting Loops use the same fundamental operating characteristics as other resectoscope working elements and electrode cutting loops. The Roei Working Element includes a handle and rod to which the disposable Roei Cutting Loops are attached. One end of the handle has a connection port for connection of a resectoscope optics element. The opposite end of the Roei Working Element handle has a connection port that accommodates a resectoscope sheath used to encase a Roei Cutting Loop. Additionally, the Roei Working Element handle provides an electrical connection box with an inlet receptacle for connection of a resectoscope's electrosurgical cable that is then attached to a monopolar electrosurgical generator. Once the Roei Working Element and Cutting Loop are attached to a resectoscope system, the Roei Cutting Loop receives electrical current from the electrosurgical generator. The electrical current transmitted to the Cutting Loop is then used to resect the targeted soft tissue.

In addition to serving as the housing for the Roei Cutting Loops, optics and electrical connections, the Roei Working Element permits translation of the axial motion of the handgrip into a circular axis movement of the Cutting Loop independent of the resectoscope sheath. This circular axis movement provides the ability for the surgeon to move the Cutting Loop in a side-to-side clockwise or

K 0509/0

pg 3 of 3

counterclockwise direction through the soft tissue, according to the operating handle position.

Performance Data

Animal testing conducted using the Roei Working Element and Roei Cutting Loops as a component of a previously 510(k)-cleared device, demonstrated that the device safely and effectively resects soft tissue. Additionally the Roei Working Element and Roei Cutting Loops when used as accessories to resectoscopes and monopolar electrosurgical generators will be in compliance with the following recognized consensus standards prior to marketing the device (1) IEC 6061-2-2, Third Ed. (1998-09): Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment; and (2) AAMI/ANSI HF 18 (2001): Electrosurgical devices.

Substantial Equivalence

The Roei Working Element and Roei Cutting Loops have the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. The minor technological differences between the Roei Working Element and Roei Cutting Loops and the predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Roei Working Element and Roei Cutting Loop are as safe and effective as the predicate devices. Thus, the Roei Working Element and Roei Cutting Loop are substantially equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 2005

Roei Medical Technologies, Ltd.
c/o Jonathan S. Kahan, Esq.
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
WASHINGTON DC 20004

Re: K050910

Trade/Device Name: Roei Working Element and Roei Cutting Loops
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FAS
Dated: June 2, 2005
Received: June 2, 2005

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

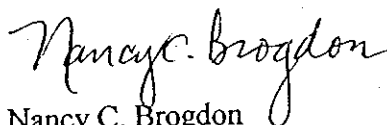
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K050910

Device Name: Roei Working Element and Roei Cutting Loops

Indications for Use:

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Prescription Use ☒
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050910